Washington State DEPARTMENT OF SOCIAL & HEALTH SERVICES

ADHD Drug Therapy Safety Edits

BACKGROUND

Clinicians, advocates, and Industry Stakeholders from around the state have gathered since early November 2005 at-monthly meetings to discuss the safe and effective use of medication therapy for ADHD. The membership of this stakeholders' workgroup included representation from the Regional Support Networks, Harborview Medical Hospital, Seattle's Children Hospital, Eastern and Western State Hospital, University of Washington, NAMI, Washington State Psychiatric Association, Washington Council of Community Mental Health Centers, Washington State Health and Recovery Services Administration (HRSA) clinical and policy staff, Client Advocates, and Pharmaceutical Industry representatives. Based on hours of clinical evidence-based discussion and expert opinion, the following is an outline of the stakeholders' ADHD Drug Therapy recommendation to ensure safe use of ADHD drugs.

NON- ENDORSING PRESCRIBERS Guidelines: *ADHD therapy safety edits apply to both preferred and non-preferred drugs.* For a non-endorsing prescriber to obtain authorization for a non-preferred drugs, the client must have tried and failed or is intolerant to at least two preferred drugs.

ENDORSING PRESCRIBERS Guidelines: *ADHD therapy safety edits apply to both preferred and non-preferred drugs.*

1. **Safety Edit - AGE**
   - **o** Age less than 5 years - requires Prior Authorization and a HRSA-approved second opinion. The ADHD drug can be continued for 30 days while the second opinion is taking place.

2. **Safety Edit - DOSAGE**

   Dosing limits for ages five and older:

   - o All doses greater than 120 mg methylphenidate, 60mg dexmethyphenidate, or 60 mg amphetamine in children less than 18 will require Prior Authorization and a HRSA-approved second opinion. Adult doses exceeding the limits will require Prior Authorization by the Medical Director; who will review clinical chart notes that must show:
     - Less risk than usual care,
     - Less cost to the state, and
     - The next step in reasonable care including tried and failed the FDA dosing.

- o If the prior authorization request is denied, HRSA will allow one last 30 days of medication for the purpose of tapering the dose to within the above accepted limits.

3. Safety Edit – COMBINATIONS

- **o** Combinations across drug types (i.e. methylphenidate *with* amphetamine) require Prior Authorization; tapers are authorized for a maximum of 30 days.
- **o** Combinations of Strattera with stimulant ADHD drugs require Prior Authorization; tapers are authorized for a maximum of 30 days.

ADHD Drugs have been added to the Washington Preferred Drug List

Drug Class	Preferred Drug	Non-Preferred Drug
Attention Deficit/Hyperactivity Disorder There will be no therapeutic substitution of these ADHD drugs at the pharmacy.	**Generic:** amphetamine salt combo dextroamphetamine dextroamphetamine SA methylphenidate methylphenidate SA **Brand:** Adderall XR® *(amphet asp/amphet/d-amphet)* Concerta® *(methylphenidate)* Focalin® *(dexmethylphenidate)* Focalin XR® *(dexmethylphenidate)* Metadate CD® *(methylphenidate)* Ritalin LA® (*methylphenidate)* Strattera® *(atomoxetine hcl)*	**Generic:** pemoline **Brand:** Adderall® *(amphet asp/amphet/d-amphet)* Dexedrine® *(d-amphetamine)* Dexedrine SA® *(d-amphetamine)* Dextrostat® *(d-amphetamine)* Metadate ER® *(methylphenidate)* Methylin® *(methylphenidate)* Methylin ER® *(methylphenidate)* Ritalin® *(methylphenidate)* Ritalin SR® *(methylphenidate)*

Limitations (dose and age) on ADHD Drugs

Drug	Dosing Limitations	Age Limitations *
Metadate ER®, Methylin®, Methylin ER®, methylphenidate, methylphenidate SR, Ritalin®, Ritalin SR®	120 mg per day	5 years of age and older
Concerta® (*methylphenidate ER)*	120 mg per day as a single daily dose	5 years of age and older
Ritalin LA® (*methylphenidate ER)*	120 mg per day as a single daily dose	5 years of age and older
Metadate CD® (*methylphenidate ER)*	120 mg per day as a single daily dose	5 years of age and older
Focalin® *(dexmethylphenidate)*	60 mg per day	5 years of age and older
Focalin XR® *(dexmethylphenidate ER)*	60 mg per day as a single daily dose	5 years of age and older
Dexedrine®, Dextrostat®, dextroamphetamine	60 mg per day	5 years of age and older
Adderall®, amphetamine salt combo, Dexedrine spansule® *(dextroamphetamine ER)*	60 mg per day	5 years of age and older
Adderall XR® *(amphetamine salt combo ER)*	60 mg per day as a single daily dose	5 years of age and older

* Children less than five require prior authorization.

Note: DAW-1 by an endorsing prescriber does not override age or dosing limits for the ADHD drugs listed.

Recommended Dosing for ADHD Drugs

*Medications Used in the treatment of Attention-Deficit/Hyperactivity Disorder

Generic Class (Brand)	Daily dosage Schedule	Duration	Prescribing Schedule
Methylphenidate			
• Short-acting (Ritalin, Metadate, Methylin)	Twice a day (BID) to three times a day (TID)	3-5 hrs	5-20mg BID to TID
• Intermediate-acting (Ritalin SR, Metadate ER, Methylin ER)	Once a day (QD) to BID	3-8 hrs	20-40mg QD or 40mg in the morning and 20 mg in early afternoon
• Extended-Release (Concerta, Metadate CD, Ritalin LA)	QD	8-12 hrs	18-72mg QD
Amphetamine			
• Short-acting (Dexedrine, Dextrostat)	BID to TID	4-6 hrs	5-15mg BID or 5-10mg TID
• Intermediate-acting (Adderall, Dexedrine spansule)	QD to BID	6-8hrs	5-30mg QD or 5-15mg BID
• Extended-Release (Adderall-XR)	QD		10-30mg QD

Clinical Practice Guideline: Treatment of the School-Aged Child with Attention-Deficit/Hyperactivity Disorder. *Pediatrics* 2001;108;1033-1044.

Generic Class (Brand)	Daily Dosage Schedule	Prescribing Schedule
Dexmethylphenidate (Focalin)	Twice a day (BID) at least four hour apart	Up to 10mg BID
Dexmethylphenidate extended release (Focaliin XR)	Once a day (QD)	Up to 20mg QD
Atomoxetine (Strattera)	QD or BID in the am and late afternoon/early evening	Up to 100mg QD in a single or BID dose

FDA Product Labeling

Additional Safety Edit for all Children– SEDATIVES/HYPNOTICS

- Sedatives and hypnotics in children less than 18 year old are limited to a one-time authorization of less than 5 doses in a 30 day period